the CHART and hypofractionated groups respectively. Two-year OS (2YS) from diagnosis was 34% for CHART and 45% in the hypofractionated group.
Conclusion: This single centre audit reflects outcome of unselected consecutively treated NSCLC patients. Patient selection for the two radiotherapy regimens was largely down to the timely availability of the next CHART session, though only CHART patients received prophylactic nodal irradiation (PNI), so smaller peripheral lesions were selected for the hypofractionated schedule when PNI was not felt to be indicated. This helps to explain the demographic differences in the two groups and means direct comparison is not possible.
Encouragingly, CHART outcome demonstrates reproducibility, with the original CHART paper (Saunders M et al 1999). Our hypofractionated outcome is similar to that previously reported (Lester et al, 2004), but despite this being the UK's most common regime, 55 Gy in 20 daily fractions remains un-validated by phase III trial data.

6586 POSTER

Cisplatin (CDDP) plus vinorelbine (VRB) as first-line treatment for patients with advanced non-small-cell lung cancer (NSCLC): molecular correlates

M. Provencio[1], R. Blanco[2], V. Alberola[3], J.R. Delgado[4], P. Diz[5], J.A. Almenarez[6], G. Lopez-Vivanco[7], J.L. Gonzalez-Larriba[8], G. Martin[9], R. Rosell[10]. *[1]Hospital Puerta de Hierro, Servicio de Oncologia Medica, Madrid, Spain; [2]Hospital de Terrassa, Servicio de Oncologia Medica, Terrassa, Spain; [3]Hospital Arnau de Vilanova, Servicio de Oncologia Medica, Valencia, Spain; [4]Hospital Virgen de las Nieves, Servicio de Oncologia Medica, Granada, Spain; [5]Hospital de Leon, Servicio de Oncologia Medica, Leon, Spain; [6]Hospital Universitario Insular de Gran Canaria, Servicio de Oncologia Medica, Las Palmas de Gran Canaria, Spain; [7]Hospital de Cruces, Servicio de Oncologia Medica, Barakaldo, Spain; [8]Hospital Clinico Universitario San Carlos, Servicio de Oncologia Medica, Madrid, Spain; [9]Hospital Clinico Universitario, Servicio de Oncologia Medica, Salamanca, Spain; [10]ICO – Hospital Germans Trias i Pujol, Servicio de Oncologia Medica, Badalona, Spain*

Background: The combination of cisplatin plus vinorelbine is a commonly used regimen for first-line therapy in advanced NSCLC. The correlation between predictive genetic markers and clinical endpoints may improve the prediction of treatment success and thereby the tailoring of chemotherapy. In this trial, predictive genetic markers of response to CDDP/VRB were examined in genomic DNA and cDNA derived from tumors and circulating tumors.
Materials: From April 2004 to January 2006, 238 chemonaive patients (pts) with stage IIIB (pleural effusion or supraclavicular lymph nodes)–IV or recurrent NSCLC were accrued at 35 sites. Treatment consisted of CDDP 75 mg/m^2 IV day 1 plus VRB 25 mg/m^2 IV or 60−80 mg/m^2 oral, days 1, 8 every 21 days. DNA samples were collected from primary tumors for the assessment of microtubule associated protein 4 (MAP4) and from serum for the checkpoint forkhead-associated and ring finger (CHFR) methylation.
Results: Data on 198 pts is available. Median age 62 years (38−80); males: 83.8%; smokers: 77.8%; PS 0−1: 95.3%; adenocarcinoma, 48.9%/ squamous 32.8%; stage IIIB: 16.7%, IV: 83.3%. Median cycles: 4 (1−12). Hematological toxicities (%pts): neutropenia grade 3−4, 17.2%; thrombocytopenia grade 3−4, 1%; anemia grade 3, 2%. Febrile neutropenia appeared in 14 cycles/10 pts (1.8%/5.1%). Non-hematological toxicities (%pts): pulmonary grade 3−4, 5.5%; nausea/vomiting grade 3−4, 8.1%; asthenia grade 3, 13.2%; pain grade 3, 6.6%; infection grade 3, 4.1%; neurotoxicity grade 3, 0.5%. Efficacy in evaluable population: CR, 2.3%; PR, 30.8%; ORR, 33.1% (95% CI 26.1−40.2%); SD, 39.7%. Median follow up of 6.7 months, median survival for the whole population was 9 months (mo), progression free survival 5.07 mo, event free survival 4.8 mo, 1-year survival 39.9%.
Conclusions: This trial confirms that CDDP/VRB is effective as first-line therapy, presenting a favourable toxicity profile in p with advanced NSCLC. A complete genomic analysis is ongoing.

6587 POSTER

A phase IB, dose-finding study of erlotinib in combination with pemetrexed in patients with advanced (stage IIIB/IV) non-small-cell lung cancer (NSCLC): a preliminary analysis of the BP18193 study

M. Ranson[1], M. Reck[2], A. Anthoney[3], A. Hanauske[4], M. Akimov[5], G. Klingelschmitt[6], H. Kletzl[7], C. Twelves[8]. *[1]Christie Hospital, Department of Medical Oncology, Manchester, United Kingdom; [2]Krankenhaus Groβ hansdorf, Department of Thoracic Oncology, Groβ hansdorf, Germany; [3]St James' University Hospital, Medical Oncology, Leeds, United Kingdom; [4]Krankenhaus St Georg, Medical Oncology, Hamburg, Germany; [5]F. Hoffmann-La Roche, Science, Basel, Switzerland; [6]F. Hoffmann-La Roche, Statistics, Basel, Switzerland; [7]F. Hoffmann-La Roche, Clinical Pharmacology, Basel, Switzerland; [8]Tom Connors Cancer Research Centre, Cancer Therapeutics, Bradford, United Kingdom*

Background: Erlotinib (Tarceva®) monotherapy has shown significantly improved survival, delayed symptom deterioration and improved QoL in patients (pts) with advanced NSCLC. This study was designed to determine the maximum tolerated dose (MTD) of the erlotinib/pemetrexed (Alimta®) combination (E/P) and to collect preliminary evidence of anti-tumour activity.
Methods: Pts were enrolled into this non-randomised open-label study if they had either failed first-line, platinum-based chemotherapy or were considered suitable for the E/P regimen. Pts received P 500–700 mg/m^2 i.v. every 21 days; E 100–150 mg/day p.o. MTD was defined as the dose below that which led to dose-limiting toxicities (DLTs) in $\geqslant$1/3 pts. The MTD cohort was then to be expanded to 12 pts for confirmation of tolerability.
Results: A total of 20 pts, median age 59 yrs, were entered into 4 cohorts: 3 (1 female) in cohort 1 (E100/P500), 6 (1 female) in cohort 2 (E150/P500), 6 (2 female) in cohort 3 (E150/P600) and 5 (2 female) in cohort 4 (E150/P700). No DLTs were reported in cohorts 1–3, but each pt reported at least one adverse event (AE). 3 pts in cohort 4 had DLTs (one skin rash with secondary infection, one grade 2 skin rash and one neutropenia, anaemia, thrombocytopenia and rash). Frequently reported AEs (any grade) included diarrhoea (in 17 pts), rash (16 pts), fatigue (13 pts), anorexia (11 pts), neutropenia (6 pts) and dyspnoea (4 pts). Serious AEs were experienced by 5 pts (33%) in cohorts 1–3 and by 3 pts (60%) in cohort 4. Following results from a separate study examining doses of P >500 mg, which did not improve efficacy over the standard 500 mg dose, it was decided to discontinue using P doses >500 mg in ongoing studies. Thus, enrolment in higher-dose cohorts for this study was prematurely discontinued and MTD could not be confirmed in an expanded cohort. Two partial responses were reported, one each in cohorts 1 and 4. Pharmacokinetic (PK) evaluation for E, its metabolite OSI-420, and for P, showed no drug–drug interaction. PK parameters were comparable when given in E/P combination and alone.
Conclusions: The data suggest that the E/P combination is well-tolerated. Full, standard, single-agent doses of both drugs were given concurrently in cohort 2 and did not lead to DLTs. Discontinuation of enrolment meant that MTD could not be confirmed but the E/P regimen warrants further investigation.

6588 POSTER

Vinorelbine (VRL) plus gemcitabine (GEM) as first-line treatment for elderly patients with advanced non-small-cell lung cancer (NSCLC): molecular correlates

I. Maestu[1], D. Isla[2], M. Pedraza[3], J. Munoz[4], J. Oramas[5], R. Garcia-Gomez[6], S. del Barco[7], B. Cantos[8], M. Taron[9], R. Rosell[9]. *[1]Hospital Virgen de los Lirios, Servicio de Oncologia Medica, Alcoy, Spain; [2]Hospital Clinico Universitario Lozano Blesa, Servicio de Oncologia Medica, Zaragoza, Spain; [3]Hospital de Leon, Servicio de Oncologia Medica, Leon, Spain; [4]Hospital Universitario Dr Peset, Servicio de Oncologia Medica, Valencia, Spain; [5]Hospital Universitario de Tenerife, Servicio de Oncologia Medica, La Laguna, Spain; [6]Hospital Universitario Gregorio Maranon, Servicio de Oncologia Medica, Madrid, Spain; [7]ICO – Hospital Josep Trueta, Servicio de Oncologia Medica, Girona, Spain; [8]Hospital Puerta de Hierro, Servicio de Oncologia Medica, Madrid, Spain; [9]ICO – Hospital Germans Trias i Pujol, Servicio de Oncologia Medica, Badalona, Spain*

Background: The clinical benefit of non-cisplatin doublets vs single-agent therapy in elderly or unfit p is still controversial. The present study focuses on the clinical outcome of VRL/GEM in elderly p and the role of functional status and comorbidities. Predictive genetic markers of response to VRL/GEM will also be examined in genomic and cDNA from tumor and circulating tumor DNA.
Materials: 145 chemonaive p with stage IIIB (pleural effusion or supraclavicular lymph nodes)-IV or recurrent NSCLC and age >70 years